The T-Cell Depletion in Unrelated Donor Marrow Study (TCD)

Data Distribution Agreement

The National Heart, Lung, and Blood Institute (NHLBI) and _____ (Name of Recipient Organization) hereby enter into this Distribution Agreement as of the date specified on the final page hereof.

PRELIMINARY STATEMENT

The National Heart, Lung, and Blood Institute (NHLBI) has supported collection of data from participants in the T-Cell Depletion in Unrelated Donor Marrow Study (TCD), hereafter referred to as "Study". This well-characterized population provides a rare and valuable scientific resource. Promoting optimal use on a national scale of such a resource will require a large and concerted effort which may exceed the research capacity of currently available Study investigators. The NHLBI and the researchers it supports have a responsibility to the public in general, and to the scientific community in particular, to encourage as rapid scientific progress as possible using these resources, subject to appropriate terms and conditions. In order to take full advantage of such resources and maximize their research value, it is important that data collected with public funds be made available, on appropriate terms and conditions, to the largest possible number of qualified investigators in a timely manner.

Data collected by the Study have been stripped of all personal identifiers but the wealth of data available on them might make possible the individual identification of some subjects. To protect the confidentiality and privacy of these participants, the Recipient who is granted access to these data must adhere to the requirements of this Distribution Agreement. Failure to comply with this Distribution Agreement could result in denial of further access to Study Data. Violation of the confidentiality requirements of this agreement is considered a breach of confidentiality and may leave requesting investigators liable to legal action on the part of Study participants, their families, or the U. S. Government.

The Study Investigators have made a substantial long-term contribution in establishing and maintaining the clinical database. The NHLBI seeks to encourage appropriate collaborative relationships by outside investigators with the Study Investigators and to ensure that the contribution of the Study Investigators is appropriately acknowledged.

DEFINITIONS

For purposes of this agreement, "Data" refers to the following information, which has been collected and recorded from Study participants through the periodic examinations and follow-up contacts conducted pursuant to the Study Investigators' contract with the NHLBI:

Data from the T-Cell Depletion in Unrelated Donor Marrow Study (TCD).

A "TCD Study Investigator" is defined as a research investigator with a current and active contract or consulting agreement with NHLBI or one of its contractors to work on the TCD Study.

RECIPIENT ORGANIZATION is (check one):
A ___ non-profit OR ____ for-profit corporation organized under the laws of the State of _____.
Or a ____ government agency governed under the laws of _____.

Principal Investigator requests access to Study data at its sole risk and at no expense to the Study and NHLBI.

Principal Investigator:
_____ , with a principal address at
_____ (**"**PI") requests access to Study data at no expense to the Study and NHLBI.

AGREED TERMS AND CONDITIONS

It is mutually agreed as follows:

1. Research Project.

    1.1 The PI requests (check one)

    __Non-Commercial Purpose Data Set
    __Commercial Purpose Data Set

    1.2. These Data will be used by Recipient's Principal Investigator solely in connection with the following research project ("Research Project"), specifically described in an attached Exhibit A: The Project description should include: project title, a 1-2 paragraph description of the objectives and design, and a brief description of the analysis plan.

Note: If the PI is requesting a Genetic/Pedigree Data Set, the Research Project description must describe a specific need for it. Investigators using these data are strongly discouraged from publishing individual pedigree structures and are prohibited from investigation into issues such as non-paternity.

1.3. The Research Project (circle one); [does][does not] involve TCD Study Investigator(s) as co-investigator(s). If the Project does involve TCD Study Investigator(s), their names are:_____ _____ and the work they will perform is described below or in an attached Exhibit B:_____ _____ _____

1.4. This Distribution Agreement covers only the above-described Research Project. Recipient will submit a completed Distribution Agreement (this document) for each research project for which Data are requested.

2. Non-transferability. This Distribution Agreement is not transferable. Recipient agrees that substantive changes made to the Research Project described above, and/or appointment by Recipient of another Principal Investigator to complete the Research Project, require execution of a new Distribution Agreement in which the new Principal Investigator and/or new Research Project are designated.

3. Publication. Prompt publication or any public disclosure of the results of the Research Project is encouraged. Recipient agrees to provide to NHLBI a copy of any manuscript or other disclosure document thirty (30) days in advance of submission for publication, in order to ensure compliance with the confidentiality requirements set forth in paragraphs 4,5,6,7,and 8 of this Agreement.

4. Acknowledgments. Recipient agrees to acknowledge the contribution of the Study Investigators in any and all oral and written presentations, disclosures, and publications resulting from any and all analyses of Data.

4.1. Collaborations/Acknowledgments. If the Research Project involves a collaboration with Study Investigators (see paragraph 1 above), then the manuscript will be reviewed by NHLBI and Recipient will acknowledge Study Investigators and/or participants as required by the Study's publications committee. In addition, the Recipient will acknowledge the source of the data by including language similar to the following either in the acknowledgment or in the text of the manuscript: 'This manuscript was prepared using a limited access dataset obtained from the NHLBI'.

4.2. Other Studies/Acknowledgments. If the Research Project does not involve a collaboration with Study Investigators (see paragraph 1 above), then the manuscripts or other disclosure documents should be submitted to the NHLBI thirty (30) days in advance of submission for publication. The manuscripts will be reviewed by NHLBI and Recipient will use the acknowledgment printed below. [The process for review of manuscripts by NHLBI is described in Attachment 1.]

"The T-Cell Depletion in Unrelated Donor Marrow Study (TCD)is conducted and supported by the NHLBI in collaboration with the TCD Investigators. This Manuscript was prepared using a limited access dataset obtained by the NHLBI and does not necessarily reflect the opinions or views of the TCD or the NHLBI."

5. Non-Identification. Recipient agrees that Data will not be used, either alone or in conjunction with any other information**,** in any effort whatsoever to establish the individual identities of any of the subjects from whom Data were obtained.

6. Use Limited to Research Project**.** Recipient agrees that Data will not be used in any research that is not disclosed and approved as part of the Research Project.

7**.** No Distribution. Recipient agrees to retain control over Data, and further agrees not to transfer Data, with or without charge, to any other entity or any individual.

8. Non-Data. Notwithstanding the definition of "Data" or the agreed Terms and Conditions of this Distribution Agreement, Recipient's obligations under this Distribution Agreement shall not extend to any information:

(a) that can be demonstrated to have been publicly known at the time of disclosure; or
(b) that can be demonstrated to have been in the possession of or that can be demonstrated to have been readily available to Recipient from another source prior to the disclosure; or
(c) that becomes part of the public domain or publicly known by publication or otherwise, not due to any unauthorized act by Recipient; or
(d) that can be demonstrated as independently developed or acquired by Recipient without reference to or reliance upon Data provided under this Agreement; or
(e) that is required to be disclosed by law, provided the Recipient takes responsible and lawful actions to avoid and/or minimize such disclosure.

9. Non-Endorsement, Indemnification. Recipient agrees not to claim, infer, or imply Governmental endorsement of the Research Project, the entity, or personnel conducting the Research Project or any resulting commercial product(s) except as described in paragraph 4. To the extent permitted by law, Recipient agrees to hold the United States Government, Study Investigators, and all other investigator(s) who generated Data and the agents and employees of each of them, harmless and to defend and indemnify all such parties for all liabilities, demands, damages, expenses, and losses arising out of Recipient's use for any purpose of Data.

10. Recipient's Compliance with IRB Requirements. Recipient acknowledges that the conditions for use of these Data are not exempt from review and have been approved by the Recipient's Institutional Review Board (IRB) operating under an Office of Human Research Protections (OHRP) - approved Assurance and in accordance with Department of Health and Human Services regulations at 45 CFR Part 46. Recipient agrees to comply fully with all such conditions. Recipient agrees to report promptly to the NHLBI any proposed change in the research project and any unanticipated problems involving risks to subjects or others. This Agreement is made in addition to, and does not supercede, any of Recipient's institutional policies or any local, State, and/or Federal laws and regulations which provide additional protections for human subjects.

11. Amendments. Amendments to this Distribution Agreement must be made in writing and signed by authorized representatives of all parties.

12. Termination. NHLBI may terminate this Distribution Agreement if Recipient is in default of any condition of this Distribution Agreement and such default has not been remedied within 30 days after the date of written notice by NHLBI's Authorized Representative of such default.

13. Disqualification, Enforcement. Failure to comply with any of the terms specified herein may result in disqualification of Recipient from receiving additional Data.

The United States Government shall have the right to institute and prosecute any proceeding at law or in equity against the Recipient for violating or threatening to violate the confidentiality requirements of this agreement, the limitations on the use of the data provided, or both. Proceedings may be initiated against the violating party, legal representatives, and assigns, for a restraining injunction, compensatory and punitive damages, mandamus, and/or any other proceeding in law or equity, including obtaining the proceeds from any intellectual property or other rights that are derived in whole or in part from the breach of the confidentiality requirements or use limitations of this agreement. In addition, Recipient acknowledges and agrees that a breach or threatened breach of the confidentiality requirements or use limitations of this agreement may subject Recipient to legal action on the part of Study subjects, their families, or both.

14. Accurate Representations. Recipient expressly certifies that the contents of any statements made or reflected in this document are truthful and accurate.

15. Duplication of Research. The recipient of the limited access data acknowledges that other researchers have access to this data, and that duplication of research is a distinct possibility.

Signatures begin on the next page.

This Distribution Agreement is entered into as of :_____
(effective date)

RECIPIENT:

Name of Recipient Organization: _____

Name and Title of Recipient's Authorized Institutional Business Official:

_____

Signature and Date of Recipient's Authorized Institutional Business Official:_____

_____

PRINCIPAL INVESTIGATOR:

Principal Investigator's Name and Title:_____

_____

Principal Investigator's Surface Mail Address:_____

_____

Principal Investigator's E-Mail Address:_____

Principal Investigator's Telephone Number:_____

Principal Investigator's Fax Number:_____

Signature and Date: Principal Investigator: _____

_____

NHLBI:

Name and Title of NHLBI's Authorized Representative: _____

_____

Signature and Date of NHLBI Authorized Representative:

_____

ATTACHMENT 1A: **NHLBI Policies for Review of Manuscripts *without* NHLBI Staff Authorship** (Revised 3/31/96)

Manuscript Review Policy

NHLBI reviews manuscripts from large-scale, Institute-initiated studies and investigator-initiated studies converted to cooperative agreements prior to their submission for publication. Clarification of criteria and procedures for this scientific review are being provided for use by NHLBI staff and investigators in these types of studies.

Purpose of NHLBI Review

The purposes of NHLBI scientific review are to keep NHLBI staff informed of activities and results of major research studies, particularly when findings or their interpretations are likely to be controversial or when new data conflict with previous reports, and to provide advice which may be considered helpful.

Almost all collaborative multicenter and complex single-center studies have a committee in charge of publications (either a Steering Committee or separate Publications Subcommittee), and NHLBI scientific staff are usually members of these committees. In this role, NHLBI staff have the same voice in approving a manuscript or abstract as other committee members. NHLBI review is a separate process, usually conducted in parallel with study-specific review**.** It may involve scientific staff other than the study's Project Scientist or Project Officer.

NHLBI review is not intended to duplicate journal review; however, many NHLBI staff are active reviewers for peer-reviewed journals and major scientific meetings. Their suggestions may be of assistance to other investigators and their comments may improve chances of acceptance by peer-reviewed journals. Such comments, generally identified as reviewers' suggestions in the letter summarizing results of the review or manuscript text rather than as specific requests for revisions, should be considered matters of collegial advice to be incorporated at the author(s)' discretion.

Conduct and Authority of NHLBI Review

NHLBI review applies to manuscripts or abstracts intended for publication or presentation using data from NHLBI-initiated programs. Submissions are assigned for initial review to the NHLBI Project Scientist or Project Officer and other scientific staff based on their expertise and availability. Reviewed manuscripts are submitted to the appropriate Division Program Director (for example**,** the Director of the Clinical Applications and Prevention Program**,** DECA**)** and then to the Division Director. Manuscript reviews are usually completed and authors notified of the outcome within three to four weeks. Abstract reviews are usually completed within one

week or less.

NHLBI review is not binding upon non-NHLBI staff, who, as private citizens, have the right to say or write what they wish. Reviewers' comments should be considered as advice. Authors should understand**,** however**,** that NHLBI staff are frequently called upon by the media to comment on particularly newsworthy or controversial papers**.**

Upon receiving the outcome of NHLBI review and comments, authors are asked to consider reviewers' comments carefully. Authors are encouraged to discuss comments with the study's Project Scientist or Project Officer, or the Division or Program Director, especially if they believe a comment has been made in error. Authors should notify the Project Scientist or Project Officer when a manuscript is accepted for publication and send a copy of the published manuscript as soon as it is available. For papers that are particularly newsworthy**,** NHLBI staff will supply the Public Information Office with a title page and abstract of the manuscript, and will notify the Office when publication is imminent and provide it with a copy of the final version.

Questions about the review process may be directed to a study's Project Scientist or Project Officer, the Division Program Director, or the Division Director.

ATTACHMENT 1B: **NHLBI Policies for Review of Manuscripts with NHLBI Staff Authorship**
(Revised 1/11/99)

Manuscript Review Policy

All manuscripts of which NHLBI staff are authors or co-authors must undergo scientific review and clearance prior to their submission for publication. Clarification of criteria and procedures for this scientific review are being provided for use by NHLBI staff.

Purpose of NHLBI Review

For collaborative studies supported by contracts, cooperative agreements, or grants, there is usually a committee in charge of publications (either a Steering Committee or a separate Publications Subcommittee), and NHLBI scientific staff are usually members of these committees. NHLBI review is a separate process, usually conducted in parallel with study-specific review**.** It may involve scientific staff other than the study's Project Scientist or Project Officer.

NHLBI review is not intended to duplicate journal review; however, many NHLBI staff are active reviewers for peer-reviewed journals and major scientific meetings. Their suggestions may be of assistance and their comments may improve chances of acceptance by peer-reviewed journals. Such comments, generally identified as reviewers' suggestions in the approval letter or manuscript text rather than as specific requests for revisions, should be considered matters of collegial advice to be incorporated at the author(s)' discretion.

Conduct and Authority of NHLBI Review

NHLBI review applies to manuscripts or abstracts with NHLBI staff as authors or co-authors. Submissions are assigned for initial review to NHLBI scientific staff based on their expertise and availability. Reviewed manuscripts are submitted to the appropriate Division Program Director or Branch Chief (for example**,** the Director of the Clinical Applications and Prevention Program**,** DECA) and then to the Division Director. Manuscript reviews are usually completed and authors notified of the outcome within three to four weeks. Abstract reviews are usually completed within one week or less. Written approval of the Division Program Director or Branch Chief and the Division Director is required.

Manuscript disapproval is binding on NHLBI employees, who must have Institute approval for their names to appear as authors or co-authors. If such a manuscript is disapproved, it must either be revised so as to be approved by the Institute or NHLBI staff who are co-authors must remove their names from it.

Staff are reminded that each author is responsible for everything in the manuscript, irrespective of his

or her involvement in any specific part of the research effort.

When appropriate, the manuscript should contain a disclaimer, indicating that what is being reported or claimed does not necessarily reflect the views of the NHLBI, NIH, or DHHS.

Criteria for Disapproval

Three primary reasons may cause a manuscript to be disapproved:

1) Concern that the analysis or interpretation may be flawed;

2) Inclusion of clinical or public health recommendations that are not consistent with or supported by (usually they simply over-extend) the data presented; or

3) Conflict with NHLBI or DHHS policies.

Differences of opinion about the scientific interpretation of results can be a reason for returning a paper without approval, if reviewers' opinions are well-founded and adequately justified. Interpretations that overstep the data; for instance, implying causality where none can be inferred, or suggesting the need for intervention when it has not been proven to be effective, can be highly embarrassing to the authors and the Institute.